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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,214	03/29/2004	Krzysztof W. Pankiewicz	08841.105019 CON 2	3043
20786	7590	11/02/2006		
KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER DESAI, RITA J	
			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/812,214

**Applicant(s)**

PANKIEWICZ ET AL.

**Examiner**

Rita J. Desai

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 27-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 27-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Claims 1-9, 27-34 are pending.

Claim 27-34 are new.

The rejection of claims 1-9 (and now also 27-34 ) under 35 USC 103 over Glonek et al in combination with Ingall et al and Zatorski et al has been withdrawn . Applicants have used Golek et al as the primary reference. The examiner has rewritten the rejection as given below

New Rejection :-

#### *Claim Rejections - 35 USC § 103*

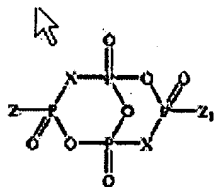
The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9, 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zatorski et al all by itself, or

Zatorski et al and Golek et al

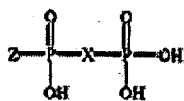
Zatorski et al is the primary references.

Applicants claims are drawn to compounds and a process of making these compound. of the formula as given in claim 1.



The process uses a compound of the formula

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and reacts it with a dehydrating agent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Zatorski which teaches a process of making the compounds in applicants specification.

They are made the same way,. The reaction says couplings but does use the term dehydrating agent, however the process is the same , except applicants claimed compounds are the intermediates in the process.

In the specifications applicants claim that these are unstable at room temperature but can state stable for a few days in a refrigerator. Page 25 lines 10-20.

Thus applicants have not isolated the intermediates and have not identified all the ones made.

Golek et al does teach the unstable linkage formed with the P-O-P groups.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The Zatorski et al reference teaches a process of making the final product. They just do not show the intermediates.

If Applicants argue that

“ Neither Zatorski teach the present

compounds or methods having the core or the recited Z, Z1, and X substituents.”

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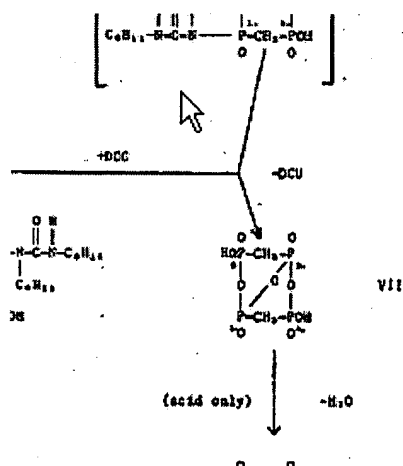
This is incorrect Zatorski et al clearly teaches the process. They just do not name the active intermediates. See the scheme. Also under the scheme 1 on page 2423 the process is clearly taught. The intermediate after the compound 9 and 12 or 11a and 12 or 11b and 12 is not separated. This compound is lyophilized with the addition of water to give the compounds as given in the introduction.

(<sup>31</sup>P NMR), the reaction was quenched by addition of water and the mixture was lyophilized. The residue was chromatographed on HPLC column to give the acetonide of BAD (15) as the major product (84.5%), together with small amounts of symmetrical pyrophosphates P<sub>1</sub>P<sub>2</sub>.

Applicants argue that the Golek reference does not disclose the compounds because of the various Z substitutions.

However these substitutions are taught in Zatorski et al .

Golek et al ( secondary reference ) teaches very clearly that an intermediate of the P-O-P linkage is formed.



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Thus it is known that an unstable intermediate is formed.

This is even more<sup>so</sup> as applicants have disclosed only two, RN 374747-72-5 and RN 374783-55-8.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 27-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for RN 374783 and 374747-72-5, does not reasonably provide enablement for all the various compounds with the different Z substitutions such as steroid carbohydrates nucleoside, aryl amino, arylalkylmercaptan. And such. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claims is very large as given by the definition of the Z terms which can be steroids, glycerides derivatives and such.

Predictability in the Art: Applicants own admission is that these compounds are highly unstable and cannot be isolated.

Guidance provided by the applicants:- In view of the instability applicants have not provided any data that these compounds have been formed.

In the specifications applicants claim that these are unstable at room temperature but can state stable for a few days in a refrigerator. Page 25 lines 10-20.

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Thus applicants have not isolated the intermediates and have not identified all the ones made.

Thus without more the compounds and the process does not show how to make the compounds of the invention.

Claims 1-9, 27-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to compounds and a process of making these compounds with the definition of Z and Z1 being an araalkyl, alkylmercaptan, arylmercaptan, carbohydrate, nucleoside, steroid, substituted glyceride and so on. The specification has no definition of what these groups encompass. There is no structure given to these groups. The specification gives no guidance to one of ordinary skill in the art the attachment of this group. The specification does not define the compound in all the above categories. Note all the groups recited for these are generic groups. The generic groups includes a plethora of compounds, which has these groups.

The expression "araalkyl, alkylmercaptan, arylmercaptan, carbohydrate, nucleoside, steroid, substituted glyceride and so on" without i.e. partial or complete structure does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject

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matter. The generic language recited without any correlation to the structure does not meet the written description requirement “as one of ordinary skill in the art could not recognize or understand the structure from the mere recitation of the generic group” Claims employing generic language at the point of novelty, such as applicants’, neither provide those elements required to practice the inventions, nor “inform the public” during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of compounds and applicants claimed expression represents only an invitation to experiment regarding possible compounds.

### ***Conclusion***

Claims 1-9, 27-34 are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

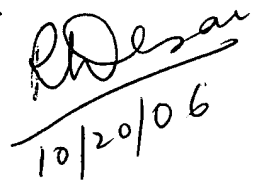
If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai  
Primary Examiner  
Art Unit 1625



10/20/06

R.D.  
October 20, 2006